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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/521,696	03/09/2000	James Keith	22058-521	2455

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BOSTON, MA 02111

EXAMINER

SEHARASEYON, JEGATHEESAN

ART UNIT	PAPER NUMBER
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1647

DATE MAILED: 05/05/2003

19

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application N .

09/521,696

Applicant(s)

KEITH ET AL.

Examiner

Jegatheesan Seharaseyon

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 28 February 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-11 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-11 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 18.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

DETAILED ACTION

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 2/28/03 has been entered. An action on the RCE follows.
2. Claims 12-20 have been cancelled. Claims 1-11 are pending.
3. The text of those sections of title 35, U. S. Code not included in this action can be found in the previous office action (Paper No: 9).

Claim Rejections - 35 USC § 112, 2nd paragraph withdrawn

4. Rejection of claims 1, 3 and 6 as vague and indefinite under 35 USC § 112 2nd paragraph is withdrawn in view of Applicant's arguments filed on 2/28/03.

Claim Rejections - 35 USC § 112, 1st paragraph withdrawn

5. Applicant's arguments have been fully considered and are persuasive. Thus the rejection of claims 1 and 2 under 35 USC § 112 1st paragraph for scope of enablement is withdrawn.

Claim Rejections - 35 USC § 102, maintained

6. The rejection of claims 1 and 6 under 35 U.S.C. § 102(a) as anticipated by Hill et al. (1998) is maintained.

Applicant has amended the claim and argues that Hill et al. lacks any teaching of complement-mediated cytotoxicity. Furthermore, it is argued that the reference

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discusses the use of IL-11 in connection with Graft-Versus Host Disease (GVHD), a disorder mediated by cytotoxic T cell lymphocytes. In addition, Applicant characterizes the Office's position with respect to the reference as "administration of IL-11 to prevent any immune-mediated disorder inherently anticipates the claimed method of complement mediated cytotoxicity". Applicant's arguments filed on 2/28/03 have been considered but are not persuasive.

Hill et al. reference teaches the administration of IL-11 to prevent lethal GVDH in a mouse bone marrow transplant model (abstract). It also teaches the administration of various amounts of IL-11 to a mammal prior to transplantation and after transplantation to treat GVDH (page: 116). In the instant reference the mammal under going tissue transplantation is at risk for GVDH. Although Hill et al. may not have fully appreciated the mechanism of the treatment; the treatment itself nonetheless meets the limitations of the claim to administer IL-11 to treat acute GVDH. Despite the fact that applicants may have been the first to characterize the effect of IL-11 on complement-mediated cytotoxicity in mammals, that effect would inherently have occurred in the mammals treated by the administration of IL-11 prior to transplantation as described by Hill et al. The Examiner notes the decision *in re Swinehart and Sfiligoj*, 169 USPQ 226, in which it was found that mere recitation of a newly discovered function or property, inherently possessed by things in prior art, does not cause claim drawn to those things to distinguish over prior art. Although the prior art did not necessarily appreciate the mechanism by which the effect was attained, it clearly teaches the same method, using the same active agent (IL-11), as the rejected claims to treat GVDH. It is furthermore

noted that the primary manifestation of complement-mediated cytotoxicity as disclosed is GVDH and rejection of organ or tissue transplants. Thus, claims 1 and 6 remain rejected under 35 USC § 102 (b) as being anticipated by Hill et al.

Claim Rejections - 35 USC § 102, maintained

7. The rejection of claim 6 under 35 U.S.C. § 102(b) as anticipated by Yang et al. (U.S. Patent No. 5,700,664) is maintained. Applicant's arguments filed on 2/28/03 have been fully considered but are not persuasive. Applicant has amended the claim and argues that Yang et al. lacks any teaching of complement-mediated cytotoxicity. Contrary to Applicants assertion that Yang et al. do not suggest administering IL-11 to treat complement mediated cytotoxicity, Yang et al. clearly contemplate administering IL-11 to treat immune cell or hematopoietic cell deficiency following a bone marrow transplantation (column 12, lines 5-7). As indicated above the Examiner notes the decision *in re Swinehart and Sfiligoj*, 169 USPQ 226, in which it was found that mere recitation of a newly discovered function or property, inherently possessed by things in prior art, does not cause claim drawn to those things to distinguish over prior art. Although the prior art did not necessarily appreciate the mechanism by which the effect was attained, it clearly teaches the same method, using the same active agent (IL-11), as the rejected claims to treat complement-mediated cytotoxicity.

Claim Rejections - 35 USC § 103, maintained

8. Claims 2-5 and 7-11 are rejected under 35 U.S.C. 103 (a) as being unpatentable over Hill et al. (1998) in view of Yang et al. (U.S. Patent No. 5,700,664) is maintained. Applicant's arguments filed on 2/28/03 have been fully considered but are not

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persuasive. Applicant argues that neither reference mentions complement-mediated cytotoxicity, nor is there any suggestions in either reference of administering IL-11 to a mammal that has been identified as at risk for, or suffering from, this type of disorder. As discussed above in paragraph 6, Hill et al. reference clearly describes the administration of IL-11 to a mammal at risk for GVDH. Although, the prior art did not necessarily appreciate the mechanism by which the effect was attained, it clearly teaches the same method, using the same active agent (IL-11), as the rejected claims to treat GVDH. The Office relied on the Yang et al. reference to teach the therapeutically effective amount of IL-11 to be administered to the mammal at risk or the patient (column 12, lines 35-45). Furthermore, contrary to Applicants assertion that Yang et al. do not suggest administering IL-11 to mammal at risk, Yang et al. clearly contemplate administering IL-11 to treat immune cell or hematopoietic cell deficiency following a bone marrow transplantation (column 12, lines 5-7). Therefore, the instant invention is obvious over Hill et al. (1998) in view of Yang et al. (U.S. Patent No. 5,700,664).

9. No claims are allowable.

Contact Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jegatheesan Seharaseyon whose telephone number is 703-305-1112. The examiner can normally be reached on M-F: 8:30-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Kunz can be reached on 703-308-4623. The fax phone numbers for

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the organization where this application or proceeding is assigned are 703-308-0294 for regular communications and 703-308-4227 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

JS
May 2, 2003



**LORRAINE SPECTOR
PRIMARY EXAMINER**